

REMARKS

This application has been amended in a manner that places it in condition for allowance at the time of the next Official Action.

Claims 1, 3-9, and 12-23 are pending in the present application. The claims have been amended to more particularly point out and distinctly claim the present invention.

In the outstanding Official Action, claims 5-9 and 12-23 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite. It is believed that the present amendment obviates this rejection.

Claims 5, 8, and 12 were rejected for allegedly being confusing for not reciting the term "*Lactobacillus plantarum*" before the term "LB931". Claims 5, 8, and 12 have been amended so that term --*Lactobacillus plantarum*-- has been inserted before the term "LB931". Moreover, applicants would like to thank Examiner Marx for her suggestion as to how to overcome this rejection.

The Official Action rejected claim 9 for containing the terms "pharmaceutical", "or other form", and "lactobacillus growth factor". Claim 9 has been amended so that the terms "or other form" and "lactobacillus growth factor" are no longer recited in the claim. Moreover, as suggested by the Examiner,

the term "pharmaceutical" has been replaced with --pharmaceutically--.

In the outstanding Official Action, claims 16, 18, 19, and 23 were rejected as failing to provide antecedent basis for compositions or products. Claims 16, 18, 19, and 23 have been amended to recite method claims.

Claim 16 was then further rejected for reciting the term "a colonization". Claim 16 has been amended to recite that the pharmaceutical composition prevents or inhibits the growth of enterobacteria.

The Official Action alleged that claim 21 was indefinite for reciting the term "via a pharmaceutical composition". However, claim 21 has been amended so that the pharmaceutical composition is selected from the group consisting of ointments, creams, liquid solutions, suppositories, and capsules. As one of ordinary skill in the art would clearly understand how to administer these pharmaceutical compositions, it is believed that the claim is definite to one of ordinary skill in the art.

Thus, in view of the above, it is believed that the claimed invention is definite to one of ordinary skill in the art.

In the outstanding Official Action, claims 1, 3-9, 12-16, and 20-21 were rejected under 35 USC §102(b) as allegedly being anticipated by, or in the alternative, under 35 USC §103(a)

as allegedly being obvious in view of REID et al. This rejection is respectfully traversed.

Applicants believe that REID et al. fails to anticipate or render obvious the claimed invention. Applicants believe that REID et al. fails to qualify as an enable publication. As the Examiner is aware, to constitute anticipation, all material elements of the claim must be found in a one prior art source, which must be enabling to one skilled in the art. *Akzo N.V. v. U.S. Int. Trade Comm.*, 808 F.2d 1471, 1 USPQ 2d 1241 (CAFC 1986). As noted in the amendment of June 10, 2002, applicants have attempted to provide comparative data showing that the bacterial strain of the present invention is distinct from *Lactobacillus plantarum* ATCC 55883. However, the *Lactobacillus plantarum* ATCC 55883 strain is not available to conduct comparative studies. Indeed, applicants submitted a statement from LGC Promochem, a distributor of ATCC products in Europe, explaining that ATCC 55883 *Lactobacillus plantarum* was a restricted patent item. The letter stated that strain ATCC 55883 was not for sale or distribution.

Nevertheless, the outstanding Official Action of August 9, 2002 alleged that it was not clear whether the request was made to the American Type Culture Collection. Moreover, the Official Action questioned the status of the availability of the strain ATCC 55883 and the meaning of "regulatory hold". Applicants believe that the letter enclosed with the amendment of

June 10, 2002 clearly indicates that the ATCC 55883 bacterial strain is unavailable to the public.

Indeed, the letter indicates that it is from LGC Promochem in partnership with ATCC. Moreover, the letter is signed by the ATCC Project Manager for LGC Promochem. Nevertheless, in the interest of advancing prosecution, applicants direct the Examiner's attention to the Declaration of Mikael G. Bergstrand. The Declaration clearly indicates that the bacterial strain ATCC 55883 is unavailable.

The Declaration explains that the Swedish company Essum was going to conduct comparative experiments for the applicants of the present application. The experiments were going to compare the bacterial strain of the present invention with the bacterial strain ATCC 55883. The Declaration indicates that the appropriate International Deposit Authority and the owner/depositor of bacterial strain ATCC 55883 were contacted on numerous occasions in an effort to obtain the strain. However, the International Deposit Authority and the depositor are either ~~unwilling or incapable of providing applicants' bacterial strain~~ ATCC 55883.

As the bacterial strain ATCC 55883 is unavailable, it is believed that the REID et al. reference fails to qualify as an enabling reference. Thus, it is believed that the rejection of claims 1, 3-9, 12-16, and 20-21 is improper and must be withdrawn.

GRAHN HAKANSSON et al. S.N. 09/623,562

In the outstanding Official Action, claims 17-19, and 22-23 were rejected under 35 USC §103(a) as allegedly being unpatentable over REID et al. in view of WO 97/02846. This rejection is respectfully traversed.

Applicants believe that the WO 97/02846 publication fails to remedy the deficiencies of REID et al. As noted above, the *Lactobacillus plantarum* ATCC 55883 strain is not available. Due to the unavailability of the strain, REID et al. fails to qualify as an enabling reference. Thus, it is believed that REID et al. in view of WO 97/02846 fails to render obvious claims 17-19 and 22-23.

In view of the present amendment and the foregoing remarks, therefore, it is believed that the present application is in condition for allowance, with claims 1, 3-9, and 12-23, as presented. Allowance and passage to issue on that basis are accordingly respectfully requested.


Attached hereto is a marked-up version of the changes made to the title and claims. The attached page is captioned

~~"VERSION WITH MARKINGS TO SHOW CHANGES MADE."~~

Respectfully submitted,

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July 9, 2003

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

IN THE TITLE:

The title throughout, declaration excepted, was amended to: --A NOVEL BACTERIAL STRAIN AND USES THEREOF [AGENT].--

IN THE CLAIMS:

The claims were amended as follows:

--1. (twice amended) A biologically pure strain of *Lactobacillus plantarum*[,] strain LB931, [which has been deposited at Deutsche Sammlung von Mikroorganismen, and] said strain has been assigned accession number DSM11918.--

--5. (twice amended) A pharmaceutical composition according to claim 3 comprising  $10^4$  to  $10^{11}$  colony-forming units, *Lactobacillus plantarum* LB931.--

--7. (twice amended) An absorbent product comprising *Lactobacillus plantarum*[,] strain LB931, [which has been deposited at Deutsche Sammlung von Mikroorganismen, and] said strain has been assigned accession number DSM11918.--

--8. (twice amended) An absorbent product according to claim 7, comprising  $10^4$  to  $10^{11}$  cfu, Lactobacillus plantarum LB931.--

--9. (twice amended) A pharmaceutical composition according to claim 5 wherein said [pharmaceutical] pharmaceutically acceptable carrier is skimmed milk, or a lactobacillus growth [factor] medium in powder [or other] form.--

--12. (amended) The pharmaceutical composition according to claim 3, wherein said Lactobacillus plantarum LB931 is in an amount of  $10^5$  to  $10^9$  cfu.--

--15. (amended) A method of preparing a [pharmaceutical] pharmaceutical composition for preventing and/or treating urogenital infections, comprising:

adding Lactobacillus plantarum, strain LB931, [which has been deposited at Deutsche Sammlung von Mikroorganismen, and] said strain has been assigned accession number DSM11918 to said pharmaceutical composition.--

--16. (amended) The [pharmaceutical composition] method according to claim 15, wherein said pharmaceutical composition prevents or inhibits the growth [a colonization] of enterobacteria [is prevented or treated].--

--18. (amended) The [absorbent product] method according to claim 15, wherein [a colonization of enterobacteria is prevented or treated] said absorbent product prevents or treats the growth of enterobacteria.--

--19. (amended) The [absorbent product] method according to claim 18, wherein said absorbent product is selected from the group consisting of a diaper, sanitary napkin, panty guard, incontinence guard and feminine hygiene product.--

--21. (amended) The method according to claim 20, wherein said *Lactobacillus plantarum* is administered to said patient via a pharmaceutical composition selected from the group consisting of ointments, creams, liquid solutions, suppositories, and capsules.--

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--23. (amended) The [absorbent product] method according to claim 20, wherein [a colonization of enterobacteria is prevented or treated] said absorbent product prevents or treats the growth of enterobacteria.--